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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,797	11/26/2003	Javier Alarcon	P-6013	4139

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EXAMINER	
BERHANU, ETSUB D	

ART UNIT	PAPER NUMBER
3768	

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,797	ALARCON ET AL.	
	Examiner	Art Unit	
	Etsub D. Berhanu	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/15/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/26/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-35, 37, 38 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcala'405 (previously cited) further in view of Lakowicz et al.'534 (previously cited).

Alcala'405 discloses a fiber optic device for monitoring chemical and/or physical conditions within the bodies of living subjects comprising: an optical conduit (Figure 1, fiber 43) having a proximal end (Figure 1, proximal end 44) and a distal end (Figure 1, distal end 45); an optical system (col. 5, lines 27-44) at the proximal end of the optical conduit comprising an electromagnetic energy emitter (Figure 1, light source 30), wherein the electromagnetic energy emitter may be a light emitting diode (col. 5, lines 45-53), and an electromagnetic energy detector (Figure 1, detector 56), wherein the electromagnetic energy detector may be a photomultiplier tube (col. 6, lines 60-64); a sensing element in optical proximity to the distal end of the optical conduit (Figure 2, elements 48 and 49), wherein the sensing element is contained within an inner surface of a tip (Figure 2, element 50), and the tip is directly attached to the distal end of the optical conduit through an adhesive connector (col. 6, lines 8-11); a connector (col. 6, lines 8-13); a sensing element attached to the distal end of the optical conduit through a connector (col. 6, lines 8-13); a sensing element attached to a polymer chain or matrix (col. 6, lines 8-11); a polymer chain or matrix directly attached to the distal end of the optical conduit (Figure 2, matrix 50 attached to distal end 45); an optical system attached to the proximal end of the optical conduit through a connector (col. 6,

lines 50-53) and the sensing element attached to the distal end of the optical conduit through a connector (col. 6, lines 8-13); and an optical conduit comprising at least one optical fiber (col. 5, lines 61-63).

Regarding claims 10 and 14, Figures 1 and 2 disclose that the polymer matrix 50 is attached to an inner surface of a tip 47, wherein the tip is directly attached to the distal end of the optical conduit 43. Regarding claims 11 and 15, Figures 1 and 2 disclose that the tip 47 is directly attached to the distal end 45 of the optical conduit, wherein the tip is attached to an adhesive substance used to adhere polymer matrix 50 to the optical conduit (col. 6, lines 8-11).

Alcala'405 further discloses that the optical elements are able to distinguish multiple wavelengths, are comprised of electrical elements for modulation of the luminescence signal received by the detector, and are comprised of optical filters (col. 6, lines 55-68 and col. 7, lines 1- 40, and Figure 2, optical filters 34 and 53); that the electromagnetic energy detector is adapted to detect energy emitted by the reporter group substantially continuously or periodically (col. 17, lines 46-54); that the optical system comprises electrical elements for modulation of the signal from the electromagnetic energy emitter (col.5, lines 45-60); that the optical system is adapted to measure the wavelength and lifetime of the luminescence signal (col. 13, lines 25-37); that the tip of the fiber optic device may be framed by metal (col. 6, lines 34-37); and that the sensing element is further adapted to be inserted through the skin of a patient (col. 7, lines 45-52).

Alcala'405 discloses all the elements of the current invention, as discussed above, except for: the sensing element containing at least one binding protein adapted to bind with at least one target analyte and at least one reporter group associated with the binding protein, wherein the reporter group is adapted to undergo a luminescence change upon binding of the binding protein to the target analyte; an optical system adapted to measure the intensity and polarization of the luminescence signal and the energy transfer efficiency of the reporter group, wherein the reporter group comprises a pair of organic dyes chosen so that the energy transfer efficiency between the pair changes upon analyte binding, wherein the

reporter group comprises a pair of fusion proteins chosen so that the energy transfer efficiency between the pair changes upon analyte binding and wherein the reporter group comprises an organic dye and a fusion protein chosen so that the energy transfer efficiency between the organic dye and the fusion protein changes upon analyte binding.

Lakowicz et al.'534 teaches the use of a sensing molecule to determine the presence or concentration of glucose in a sample, wherein the sensing molecule has a detectable quality that changes in a concentration-dependant manner, contains at least one binding protein adapted to bind with an analyte, at least one reporter group that undergoes a luminescence change upon binding of the binding protein to the analyte, the luminescence change including a detectable change in fluorescent decay time and a reference group (col. 3, line 66 – col. 5, line 25), wherein fluorescein is the reporter group and rhodamine is the reference group. It is noted that fluorescein and rhodamine are excited at different wavelengths and emit light energy at different wavelengths (see Chick et al.'789, col. 4, lines 47-57 and col. 5, lines 13-23 and lines 62-67).

Alacala'405 teaches that luminescent materials sensitive to chemical conditions may be employed in the fiber optic device, provided the luminescent time decay parameters of the luminescent material vary repeatedly with the conditions of the environment (col. 17, lines 31-38). It would have been within the skill in the art to substitute the sensing molecule of Lakowicz et al.'534 for the luminescent material of Alcala'405 since Alacala'405 teaches that luminescent materials sensitive to chemical conditions may be employed in the fiber optic device, provided the luminescent time decay parameters of the luminescent material vary repeatedly with the conditions of the environment and Lakowicz et al.'534 provides details of one such luminescent material.

Lakowitz'534 also teaches that glucose binding could be detected by changes in emission intensity, polarization, lifetime or energy transfer efficiencies (col. 4, lines 64-67, col. 5, lines 1-3, and col. 6, lines 28-30).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the optical system of Alcala'405 to measure luminescence intensity, polarization, and the energy transfer efficiency of the reporter group, as taught by Lakowitz'534, since such spectral changes can be used to detect glucose binding.

Lakowitz'534 also teaches that the reporter group may be comprised of a pair of organic dyes which display resonance transfer energy upon glucose binding (col. 5, lines 16-25).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sensing system of Alcala'405 by using a pair of organic dyes, as taught by Lakowitz'534, since glucose concentration can be measured due to a change in the fluorescent intensity of the reporter group upon glucose binding.

Lakowitz'534 also teaches that the reporter group may be comprised of a pair of fusion proteins which, upon binding with glucose, show a change in their energy transfer efficiency (col. 5, lines 54-57).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sensing system of Alcala'405 by using a pair of fusion proteins, as taught by Lakowitz'534, since glucose concentration can be measured due to a change in the energy transfer efficiency of the reporter group upon glucose binding.

Lakowitz'534 also teaches that a biosensor may include both an organic dye and a fusion protein that exhibit an energy transfer efficiency upon glucose binding (col. 9, lines 44-61).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sensing system of Alcala'405 by using an organic dye and a fusion protein, as taught by Lakowitz'534, since glucose concentration can be measured due to a change in the energy transfer efficiency of the reporter group upon glucose binding.

3. Claims 36 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alcala'405 further in view of Lakowicz et al.'534, as applied to claim 1 above, and further in view of Darrow et al.'651 (US Application No. 2002/0043651).

Alcala'405 further in view of Lakowicz et al.'534 discloses all of the elements of the current invention, as discussed in paragraph 2, except for the device comprising at least one reference group, wherein the reference group and reporter group are excited at the same wavelengths and wherein the luminescence of the reporter group and reference group are detected at the same wavelength.

Darrow et al.'651 teaches the use of a reference group having excitation and emission wavelengths similar to a fluorophore of interest while using a phase-modulation method in order to minimize instrumental errors (page 24, sections [0306] and [0310]).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the sensing element of Alcala'405 further in view of Lakowicz et al.'534 to include a reference fluorophore having excitation and emission wavelengths similar to the fluorophore of interest, since it would minimize instrumental errors. It is noted that the sensing element discussed in Example 5 of Lakowicz et al.'534 uses the phase-modulation method discussed in Darrow et al.'651.

Response to Arguments

4. Applicant's arguments with respect to claims 1-42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERIC F. WINAKUR
PRIMARY EXAMINER

EDB